



Researched Abuse, Diversion and Addiction-Related Surveillance System

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RADARS[®] System 11th Annual Scientific Meeting



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Each year the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS[®]) System Annual Scientific Meeting strives to connect industry, academia and regulatory experts from across the world to discuss the latest trends in prescription drug abuse, misuse, and diversion. This year we focused on **Beyond the Label: Prescription Opioid Abuse.**

In addition, the RADARS System held its fourth annual international pre-symposium focused on the global experience with prescription drug misuse. We presented data from multiple countries as we discussed *Global Insights in Prescription Drug Misuse*.

RADARS® System 11th Annual Scientific Meeting and

International Pre-Symposium

Speakers

RADARS

Richard Chapman, PhD
Theodore J. Cicero, PhD
Richard C. Dart, MD, PhD
Nabarun Dasgupta, MPH, PhD
Michael Gilbert, MPH
Tara Gomes
Jody L. Green, PhD, CCRP
Janetta L. Iwanicki, MD
Scott P. Novak, PhD
Judy Staffa, PhD, RPh





Richard Chapman, PhD

Director of Health Economics -Institute for Clinical and Economic Review (ICER)

ICER's Report on Comparative Value of Abuse Deterrent Formulations of Opioids: Draft Results

Conclusions:

- ICER's objective is to estimate and compare the costs and benefits of using ADF opioids or non-ADF opioids for chronic pain
- ICER's results suggest ADF opioids substantially reduce incidence of opioid abuse relative to non-ADF formulations among patients initially prescribed these drugs for therapeutic purposes, but with increased costs to the health system.
- Further research is required to ascertain how the balance of reduced diversion of prescribed opioids versus increased use of other legal and illicit opioids affects clinical and economic outcomes in these populations.



Theodore J. Cicero, PhD

John P. Feighner Professor of Psychiatry, Department of Psychiatry-Washington University in St. Louis School of Medicine

RAPID Analysis of Routes of Administration: Oral to Non-Oral Transitions

Conclusions:

- Researchers and Participants Interacting Directly (RAPID) is a subset of RADARS[®] System Survey of Key Informants Patients Program.
- Most users start with oral use.
- Progression to snorting/injecting the most common pathway.
 - o Tolerance to oral use
 - o Seeking a better high
 - o Dependent on drug type/formulation
- Not a unidirectional pathway
- Many persist in using opioids orally, even after
- starting non-oral use, for a variety of reasons. o Availability/Convenience
 - o Fear of adverse events when using certain drugs non-orally.



Presentations



Richard C. Dart, MD, PhD

Executive Director, RADARS[®] System – Denver Health and Hospital Authority

Cross-border Trafficking of Prescription Oxycodone Products Manufactured in Canada

Conclusions:

- Illicit trade of prescription oxycodone products from Canada to the US is reported.
- This trade is not limited to states near the US-Canada border.

Welcome and RADARS System 2016 Data Updates

Conclusions:

% Drug Overdose Deaths Involving Selected Drugs: 2010, 2014, 2015



• ADFs

o Adcoms galore: Opana ER, RoxyBond and beyond

o FDA will continue to approve drugs with ADF o Institute for Clinical and Economic Review (ICER)

- Heroin/Fentanyl
- Pain Treatment

o CDC Guidelines

o What is the appropriate balance?

Abuse Deterrent (Tamper Resistant) Formulations State of the Evidence 2017

Conclusions:

• Introduction of oxycodone ER was followed by improved outcomes related to oxycodone ER

- Other opioids have increased over the same time period (heroin)
- The results are similar in 3 different countries with different baseline conditions, different measurement instruments and timeframes.
- The early initial decrease in oxycodone ER contrasted with increases for most other opioids during the first year or more, but was then followed by decreases for almost all opioids.
- Multiple sources of bias and confounding are present; however, we conclude that none of these accounts for the observed decrease.

Nabarun Dasgupta, MPH, PhD

Senior Scientist, RADARS® System -Denver Health and Hospital Authority



Michael Gilbert, MPH

Epidemico

Darknet Drug Markets: Supply Chains, Stakeholders, and Opportunities for Public Health

Conclusions:

- Global history of fentanyl-heroin
- What are cryptomarkets?
- How do they interact with established drug supply chains for fentanyl-heroin
- Discussion: What are the implications for public health and surveillance?

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Presentations



Tara Gomes

Scientist—St. Michael's Hospital

Opioid Surveillance and Policy Evaluation: A Canadian Perspective

Conclusions:

 PMP data now linked to broad health services data in Ontario

• National leadership leading to improved infrastructure for national surveillance

• Ongoing Monitoring of anticipated and unanticipated impacts of policies/programs

o Fentanyl Patch 4 Patch province-wide implementation

o Delisting of high strength opioid formulations



Jody L. Green, PhD, CCRP

Director—Canadian Consumer Product and Pharmaceutical Safety Inc. Director of Research Administration, Rocky Mountain Poison & Drug Center—Denver Health and Hospital Authority

RADARS® System International Data Updates by Region

Conclusions:

• A mosaic approach to surveillance provides valuable insight from multi-dimensional perspectives

o UK and France endorsements match dispensing

- o Fentanyl and morphine in Spain were endorsed more frequently than expected by dispensing
- o While oxycodone use is increasing in Germany, endorsements were low, but methadone was endorsed more than expected
- o In Italy, the increase in oxycodone dispensing is reflected in treatment centre endorsements

• Each of the programs presented target different facets of prescription opioid abuse, misuse, and diversion

• While magnitude and patterns vary, heroin, THC, prescription opioids and benzodiazepines commonly abused/misused in many countries



Janetta L. Iwanicki, MD

Associate Medical Director, Rocky Mountain Poison & Drug Center – Denver Health and Hospital Authority

Behind the Opioid Epidemic – Fentanyl, Immediate-Release Opioids, and Mortality

Conclusions:

• IR medication abuse impacts a much larger absolute number of individuals in the US than ER

- For the greatest public health impact, interventions to decrease prescription opioid abuse in the US should include both IR and ER formulations
- NVSS mortality data has significant limitations in interpretation
- Appropriate and timely interventions require product specificity and earlier data availability

• Adding complementary Poison Center data may provide specificity, nuance, and earlier intervention



Scott P. Novak, PhD

Director and Senior Research Scientist, Substance Abuse Research and Treatment, Public Health Center – Battelle Memorial Institute

Comparative Assessments of the Prescription Drug Abuse Climate in Europe and the United States: Scientific, Regulatory, and Cultural Factors

Conclusions:

• Web panels can be very helpful for monitoring trends, even in the E.U.

- Modifications can help improve precision of estimates
- Is the E.U. on the same trajectory as U.S., circa 1995-2000?

• How does the flow of information across the Internet and travel create new opportunities

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Presentations

Judy Staffa, PhD, RPh

Associate Director for Public Health Initiatives, Office of Surveillance and Epidemiology – U.S. Food and Drug Administration

Evaluating the Impact of Abuse Deterrent Formulations: Methodological Challenges in Postmarketing Data

Conclusions:

• FDA continues to support development of effective abuse-deterrent opioid products and rigorous evaluation of their impact -- just one part of multipronged effort to address opioid crisis

• Continue to work with drug manufacturers through PMRs to improve postmarket studies – publicly share results

• Working with other federal agencies to develop new data resources and enhance existing ones

• FDA contracted access to poison control center and treatment center data in 2016

• Broad Agency Announcement (BAA) issued in 2016, soliciting research proposals in this area

• Public scientific meeting this summer

o How best to address current challenges in this area

o Development of better data sources, linkages, study designs, outcome measures

Michael Gilbert, MPH illustrates the darknet drug market with a role playing activity



Meeting attendees enjoyed a networking reception following the International Pre-Symposium



Dr. Richard Dart, MD, PhD leads a panel discussion with the Annual Meeting speakers





RADARS[®] System Offers Wide Range of Services Both Domestically and Internationally

The RADARS System data have been utilized by manufacturers, regulatory agencies and medical and public health officials to characterize and monitor prescription drug abuse, misuse and diversion.

The data have been presented at several US Food and Drug Administration (FDA) advisory committee meetings and scientific meetings as well as in reports to the FDA, new drug applications, labeling claims, post market requirements, and Risk Evaluation and Mitigation Strategies (REMS) evaluations. Data may also be used for the development of interventions, to assess the impact of interventions and to monitor ever-changing market trends.

The RADARS System is composed of a mosaic of programs which target diverse populations. Data from these RADARS System programs are triangulated to provide a comprehensive picture of prescription drug abuse, misuse and diversion. Triangulation is an approach used in many fields of research and is especially useful in the study of hard to reach or hidden populations, such as prescription drug abusers. No single data source is expected to provide complete and representative information about a given population, but when considered together, multiple data sources strengthen the credibility of findings, reduce the risk of false

See services available through the RADARS® System

interpretations, and provide a more complete and comprehensive perspective on the behaviors of the covert population.

The RADARS System has helped clients meet pre- and post-market regulatory and business requirements since 2006. These services are customized to meet specific regulatory and business needs and may include but are not limited to the development of studies, formal epidemiological studies including protocol and statistical analysis plan development, quarterly and annual surveillance reports, and ad hoc analyses/reports as requested.

The RADARS System publishes several articles each year in noteworthy peer-reviewed journals, including the New England Journal of Medicine, JAMA Psychiatry, the Journal of Pediatrics, Drug and Alcohol Dependence and the Clinical Journal of Pain. Further, RADARS System data are regularly presented at scientific conferences throughout the world.

